UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A BLUE CROSS AND BLUE SHIELD OF LOUISIANA, HMO LOUISIANA, INC., and DAVID MITCHELL, individually and on behalf of all others similarly situated, Plaintiffs, v. CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, ANTHONY INSOGNA, and JEROME ZELDIS, Defendants.	Case No. 1:23-cv-07871

REPLY BRIEF IN SUPPORT OF
DEFENDANTS CELGENE CORPORATION AND
BRISTOL MYERS SQUIBB COMPANY'S MOTION TO DISMISS

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Plaintiffs claim that for years, Celgene "lied" essentially every time it stood before the PTO and federal courts on its Pomalyst patents. They claim that though the infringement suits here spanned years hard-fought by sophisticated counsel, with generics who had every reason to try to invalidate Celgene's patents, those suits were utter shams and no one ever noticed. And they claim that though the settlements (disclosed voluntarily to Plaintiffs before they amended) contain no payments, there *must be* large and unjustified payments *somewhere* that Plaintiffs will "discover" in the future. These slipshod allegations are not plausible; they're fantasy. Were Plaintiffs to get their way, *every* settlement licensing entry prior to patent expiry would invite antitrust scrutiny; *every* patent applicant who distinguishes prior art before the PTO would face claims of fraud on the PTO, despite Rule 9(b); and *every* patentee would face antitrust damages for following the Hatch-Waxman statute's process for suing multiple generics seeking to sell copies of its product.

In their Opposition, Plaintiffs avert their eyes from the record incorporated into their Amended Complaint. They refuse to engage with the reality that every source they claim was fraudulently withheld from the PTO was either expressly disclosed, or cumulative of another that was. Rather than defend the sufficiency of their allegations under Rules 9 and 12(b)(6), Plaintiffs simply restate their deficient allegations, or fashion new ones they never pleaded. This sleight of hand does not save their Amended Complaint, and this Court should dismiss.

ARGUMENT

I. PLAINTIFFS' CLAIMS MUST EACH BEAR LEGAL SCRUTINY.

Plaintiffs do not even reach the substance of their claims before running off track. Insisting that they did not intend to pursue separate claims as to the settlements, patents, and litigations, Plaintiffs argue that they can evade scrutiny of their individual claims so long as they plead them together as a "whole." Opp. at 14, 28 n.128. That is not the law. Even where antitrust claims "are interrelated and interdependent," the Court "must . . . analyze the various issues individually."

City of Groton v. Conn. Light & Power Co., 662 F.2d 921, 928 (2d Cir. 1981); *see also Eatoni Ergonomics, Inc. v. Rsch. In Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because these alleged instances of misconduct are not independently anti-competitive, . . . they are not cumulatively anti-competitive either."); *Valassis Commc'ns, Inc. v. News Corp.*, 2019 WL 802093, at *9 (S.D.N.Y. Feb. 21, 2019) ("[I]t is unlikely that multiple independently lawful acts can come together to create an unlawful monopoly 'broth' from which antitrust injury can arise."). Combining legally deficient claims changes nothing: "the sum of zero and zero is zero," because "a series of unilateral acts that do not violate the antitrust laws may [not] be aggregated into an unlawful 'course of conduct.'" *Eatoni Ergonomics, Inc. v. Rsch. In Motion Corp.*, 826 F. Supp. 2d 705, 710 (S.D.N.Y. 2011). This is particularly so here, where immunities apply. *E.g.*, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) ("Plaintiffs may not use litigation conduct to support a claim of an overall scheme to monopolize if they cannot prove that the litigation was a sham."). Plaintiffs' settlement and patent claims must each state claims; that they were pleaded together does not change that.

II. PLAINTIFFS' REVERSE PAYMENT THEORIES FAIL BECAUSE THEY DO NOT PLAUSIBLY PLEAD ANY LARGE AND UNJUSTIFIED PAYMENTS.

Plaintiffs repeatedly attempt to skirt the requirements of *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013), to plead a "large" and "unjustified" payment in order to bring antitrust scrutiny on patent settlements. Plaintiffs insist that even though the Amended Complaint "does not allege a stand-alone reverse payment claim" (a critical concession in itself), they can nevertheless proceed with reverse-payment allegations as "part of a monopolization scheme" "[*w*]*hether or not the payment is large/unjustified*." Opp. at 28 n.128 (emphasis added). No court has ever sustained such an abandonment of the *Actavis* elements; *Actavis* is binding, and Plaintiffs' attempt to sustain a reverse payment claim without pleading a large and unjustified payment is frivolous. Plaintiffs

themselves acknowledge (Opp. at 37-38) that allowing such a claim to proceed where the alleged "payment" turns solely on "*when* the generic can sell its product" would subject "*all*" patent settlements to antitrust scrutiny—the result the Supreme Court never intended. *See Actavis*, 570 U.S. at 151-52.

Plaintiffs confirm that the core of their reverse payment theory is that the three challenged settlements simply *must* each have been tainted by multi-hundred-million-dollar "payoffs" because why else would the generics settle? In Plaintiffs' view—years-removed and unsupported by any judicial or administrative finding adverse to the patents—Celgene's patents were "weak"; the generics opted to "forgo . . . immediate profits"; and—in a grand, conclusory leap—therein lies the payment. Opp. at 10-11. Rather than respond to the legal deficiencies in this theory (*see* MTD at 9-20), Plaintiffs simply double down on their contention that the alleged payment "exceeds $300 million." Opp. at 11. Where the Court can actually find any such "payments" in the settlements (MTD Exs. A-C) is unsaid, and Plaintiffs do not dispute that their "valuation" does not correlate in any way to any of the three "forms" of payment they allege. Opp. at 11; MTD at 18-20 (explaining absence of link). Nor do they dispute that the "$300 million" is not a payment from Celgene—in any form—but rather, is Plaintiffs' back-of-the-envelope calculation of what the generics would have earned had they launched generic Pomalyst in 2020, without an adjudication of the infringement suits. No court has ever permitted a plaintiff to proceed past 12(b)(6) for claiming a compromise of patent life to itself be a "payment." Plaintiffs know this, and so they seek delay—insisting their "payment" theory will be sorted out "by discovery." Opp. at 11.

As Celgene explained (MTD at 6-9), Plaintiffs' approach flies in the face of *Actavis* and the narrow exception it established to the general rule that patent settlements do not trigger antitrust scrutiny. "[C]ommonplace" and "familiar" forms of settlement, like "allowing the generic

manufacturer to enter the patentee's market prior to the patent's expiration" via an early entry license, remain entirely lawful. *Actavis*, 570 U.S. at 152, 158; *see FTC v. AbbVie, Inc.*, 976 F.3d 327, 359 (3d Cir. 2020) ("[U]nder *Actavis*, an agreement does not run afoul of the antitrust laws if it simply allows a generic company to enter a market before patent expiration." (cleaned up)). Only when a complaint alleges *facts* "[]sufficient for the Court to make a reasonable estimate of the settlements' value," so as to plausibly show the settlement conveyed a large and unjustified payment, does the complaint proceed to discovery. *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *19 (S.D.N.Y. Sept. 22, 2015); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) (agreeing with "those courts that . . . have required that the plaintiffs plead information sufficient 'to estimate the value of the term,'" at least to the extent of determining whether it is "large" and "unjustified" (quoting *Actos*, 2015 WL 5610752, at *13)). None of Plaintiffs' "three forms" of payment (Opp. at 11), comes close to that threshold.

A. Plaintiffs Fail to Salvage Their Allegations that the Challenged Settlements "Protected" Unrelated Settlements as to a Different Drug, or Explain How Any Such Protection Amounted to a "Payment."

In their Amended Complaint, Plaintiffs said that the Pomalyst settlements were "designed to protect" separate settlements, involving separate patents and litigation, on the medicine Revlimid. Am. Compl. ¶¶ 327-28. Plaintiffs have copies of the three challenged Pomalyst settlements, though, and they were unable in their Amended Complaint to plead a single respect in which those settlements "protect" Revlimid. MTD at 15-16. Their Opposition continues to ignore this, but it is dispositive: Plaintiffs have identified no Pomalyst settlement provision that even references Revlimid; to the contrary, they plead that the two products are entirely separate "relevant product market[s]" unto themselves (Am. Compl. ¶¶ 388, 393), and Plaintiffs' attempts to bootstrap allegations as to unrelated settlements simply fail.

The motion to dismiss pointed out several additional problems with this theory (MTD at 15-16), starting with: it has nothing to do with any alleged delay in the sale of generic Pomalyst. "Protection" of *Revlimid* (even if Plaintiffs had any basis to plead such) would have nothing to do with this case, which is solely about alleged overcharges on *Pomalyst*. So, walking away from their pleaded theory that the Pomalyst settlements somehow "protected" the Revlimid settlements, Plaintiffs now argue the opposite—that the Revlimid settlements were *themselves* payments to delay entry on Pomalyst. *See* Opp. at 32-33. In other words, whereas Plaintiffs pleaded that the Pomalyst settlements delayed generic Revlimid, now they claim the Revlimid settlements delayed generic Pomalyst. But this theory was not pleaded, and there are zero plausible allegations to support it. Plaintiffs also now argue for the first time that: "there was a risk that generic Pomalyst could—at least theoretically—take some sales away from generic (and brand) Revlimid." *Id.* at 33. This "theoretical" risk is nowhere in the Amended Complaint. The same goes for Plaintiffs' new argument, again supported by no citation, that the *Pomalyst* settlements somehow enabled generics to "milk maximum profits out of" an alleged "*Revlimid* monopoly profit share." *Id.* (emphasis added). These new theories are all made up out of whole cloth. Plaintiffs had copies of the settlements before amending their complaint—the time to plead such theories, on the basis of actual provisions therein, was when they amended, not on the fly in their Opposition.

Plaintiffs also attempt to cast a pall over the *timing* of certain Pomalyst and Revlimid settlements. *Id.* at 32. In particular, Plaintiffs argue that "Alvogen, Apotex, and Hetero appear to have settled the Revlimid and Pomalyst patent litigations around the same time." *Id.* at 32 & n.155.[1] *But Alvogen, Apotex and Hetero are not the three generics that Plaintiffs allege were*

[1] Plaintiffs attempt to bolster this new theory with a newly drawn "Figure A," but it is wholly unclear what the figure conveys, and of course, graphics do not substitute for cognizable allegations.

"paid off"; those are instead Natco, Aurobindo and Teva. Am. Compl. ¶¶ 316, 346, 356. This theory is not just absent from the Amended Complaint—it is wholly inconsistent with it. In any event, it is unsurprising, and not remotely unlawful, to settle concurrent litigations near in time—or even, "simultaneous[ly]." *Actos*, 2015 WL 5610752, at *17 (where two "early-entry . . . licenses [are] permissible settlement terms under *Actavis* . . . the simultaneous grant of both does not render either license unlawful"); *see Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 714-16 (7th Cir. 2022) (fact of multiple sets of early-entry settlements, entered into simultaneously as to two different markets for the same product, stated no antitrust claims).

What cases Plaintiffs do cite in support of their "protecting Revlimid" theory are wholly distinguishable—they all involved "idiosyncratic" allegations about: settlements specifically designed to allow for an "anticompetitive product-hop" between different drugs, *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis*, 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) ("*Namenda*"); two written agreements expressly "incorporated into" one another, *In re Impax Labs., Inc.*, 2019 WL 1552939, at *21 (F.T.C. Mar. 28, 2019); co-promotional arrangements as to separate drugs expressed in a single agreement, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 334-37 (D.R.I. 2017); an alleged no authorized generic ("no-AG") agreement, *In re Xyrem Antitrust Litig.*, 555 F. Supp. 3d 829, 852 (N.D. Cal. 2021); and below-market royalty "supply agreements," *AbbVie*, 976 F.3d at 357. None of these things are pleaded here, and they are no basis for this Court to become the first to hold that it was somehow unlawful for Celgene to litigate and settle different cases on different products at similar points in time.

B. Plaintiffs' Early-Entry License Allegations Fail Under *Actavis*.

Plaintiffs have no authority to cite for their proposition that "removing the risk of forfeiture" (Opp. at 34) of 180-day statutory exclusivity constitutes a payment. So Plaintiffs

instead seek to analogize to several cases where something *more* was alleged. But those cases only confirm that the Amended Complaint offers nothing more.

First, Plaintiffs rely on *Staley v. Gilead Sciences, Inc.*, 446 F. Supp. 3d 578 (N.D. Cal. 2020), as support for their "protection of the risk" allegations—that is, their allegations that Celgene's settlements with Natco and Aurobindo provided "protection" against the "risks" that these two first-filer generics could forfeit their statutory exclusivity. But *Staley* undermines Plaintiffs' theory. In *Staley*, plaintiffs pleaded that a sole first-filer generic "had *already* forfeited the 180-day ANDA Exclusivity" at the time of the patent settlement. *Id.* at 612 (emphasis added) (cleaned up). Accordingly, *Staley* reasoned that the challenged settlement provision "was essentially 'resurrecting' ANDA Exclusivity" that no longer existed. *Id.* (cleaned up). Plaintiffs plead no such thing here, nor could they: Natco and Aurobindo never forfeited their exclusivity, and so Plaintiffs cannot plead that Celgene did anything to "resurrect" it. *Staley* also turned on additional "indicators of anti-competitiveness," specifically, that one of the generics' licensed early-entry dates was only six weeks before patent expiry. *Id.* Here, the settlements license generic competition beginning in 2026, five years before patent expiry. *See* Am. Compl. ¶¶ 201, 314.

Second, Plaintiffs cite *Namenda*'s dicta that the sufficiency of allegations of payment is "better decided on a motion for summary judgment, after discovery has taken place." Opp. at 35-36, 36 n.173 (quoting 2016 WL 4992690, at *14). But, as noted above, Plaintiffs ignore *Namenda*'s rationale, which turned on the particular allegations present in that case but *not* in this case (or in *Actos*, which did dismiss at 12(b)(6)): an alleged "anticompetitive product-hop"—that is, an alleged "second anticompetitive effect . . . allowing the Company to complete its anticompetitive 'hard switch' strategy.'" 2016 WL 4992690, at *15. (The "product-hop" in that case involved the reformulation of a product, from immediate release to extended release, near

patent expiry. *Id.* at *3-4, *15.) It was those particular allegations that were "idiosyncratic enough to distinguish the effects of the early-entry licenses granted to the Generic Defendants from those at issue in *Actavis* and *Actos*, and to require discovery to determine whether the early-entry licenses were in fact anticompetitive." *Id.* at *15. Without those allegations, *Namenda* confirmed, "the settlement terms [did] not appear anticompetitive." *Id.* Here, Plaintiffs concededly do not even attempt to allege any such "product-hop," and so there is no issue to defer to discovery.

Finally, Plaintiffs waive any response to Celgene's argument (MTD at 14-15) that, even if "protection" against a "risk" of forfeiting 180-day exclusivity were somehow a cognizable form of payment, the Amended Complaint pleads such "protection" only as to Natco and Aurobindo, saying nothing about the other four first filers, nor that, as a matter of law, *any and all of the first filers may participate in the others' 180-day exclusivity so long as one of them retains it*. As Celgene explained (*id.*), that is why Plaintiffs are unable to plead that either Natco or Aurobindo faced even a "risk" of losing out on 180-day exclusivity. Thus, as a matter of law, these settlements could not be said to have unlawfully protected against a non-existent risk. Plaintiffs' silence on this fundamental legal flaw in their theory speaks volumes.

C. Acceleration Clauses Do Not Trigger Antitrust Scrutiny Under *Actavis*.

Plaintiffs concede (Opp. at 36 & nn.174-75 (collecting cases)) that a settlement provision accelerating competition cannot *on its own* amount to a reverse payment; only when alleged as "part of" an otherwise unlawful reverse payment settlement have such clauses triggered antitrust scrutiny. There are no such allegations here. As explained above, both of Plaintiffs' first two payment theories fail, and they have withdrawn the other.[2]

[2] Plaintiffs no longer argue that the settlements' confidentiality means they contained payments. Am. Compl. ¶ 330.

Plaintiffs cite (Opp. at 35) two out-of-circuit cases for the proposition that this Court should ignore its decision on acceleration clauses in *Actos*. But both *Xyrem* and *Loestrin* involved wholly distinct theories that have no application here—*i.e.*, "no-AG" and "co-promotional agreement" theories. *Supra*, Section II.A. Plaintiffs fail to explain why this Court should part ways with *Actos* and conclude that acceleration clauses, which operate to bring generic competition earlier, constitute unlawful reverse payments in themselves. Plaintiffs offer no explanation because there is none.

In sum, Plaintiffs fail to identify any case that supports any one of their three reverse payment theories. And despite Plaintiffs' efforts to attach ever more hyperbolic labels to the alleged reverse payments, that should not obscure that they have failed to plead sufficient *facts* for this Court to conclude that any large and unjustified payment was included in the settlements.

D. Plaintiffs' Strawman Arguments Do Not Advance a Reverse Payment Claim.

Plaintiffs enlist (Opp. at 34-39) a battalion of strawmen to knock down. Because Celgene never made these arguments, they are addressed only briefly (to the extent not addressed above):

First, Plaintiffs argue (Opp. at 35) that "noncash payments are actionable under *Actavis*." Celgene never claimed otherwise—its position is simple: none of the challenged settlements contain large, unjustified payments—cash or otherwise—to the generics. *See, e.g.*, *Actos*, 2015 WL 5610752, at *20 ("[S]ome settlements with non-cash settlement terms may provide a basis for an *Actavis* reverse payment claim[;] the settlement agreements in this case do not.").

Second, Plaintiffs argue (Opp. at 35 & n.169) that Celgene set a "heightened pleading standard for reverse payments." That is misdirection. Both sides agree that under *Actavis* Plaintiffs must plead facts sufficient for a court to conclude that a specific alleged payment was large and unjustified. To the extent Plaintiffs suggest some other standard governs because their

reverse payment claim purportedly is not "stand-alone" (*id.* at 28 n.128), they are wrong. No court applies different standards depending upon whether the plaintiff considers its claim "stand-alone."

Third, Plaintiffs contend (Opp. at 35) that "precise figures are not required at the motion to dismiss phase" for the alleged payment. Celgene never claimed that Plaintiffs must allege a payment of, say, $300 million and 14 cents; rather, Celgene explained that Plaintiffs' conclusory figures, reflecting only allegedly forgone revenues, are legally irrelevant. MTD at 18-20. Plaintiffs must plead *facts* that would allow a court to determine whether any alleged payment is "large" and "unjustified." Conjured figures are *not* sufficient where they amount to "labels . . . without substance." *City of Pontiac Police & Fire Ret. Sys. v. BNP Paribas Sec. Corp.*, 92 F.4th 381, 415 (2d Cir. 2024). No court has ever held that where a generic agrees to respect patents until a licensed entry date (agreements of the type reached every day in patent litigation), and forgoes revenue it could have earned had it launched its product even earlier (were it to somehow get around the patents), that a "calculation" of such forgone revenue is somehow a "reverse payment."

Fourth, attempting to justify doing their back-of-the-napkin mathematical exercise only as to the Natco settlement, Plaintiffs respond (Opp. at 38) by pointing to a passing reference to Aurobindo made in that calculation of purportedly forgone revenue. But what Plaintiffs simply cannot point to—as to *any* of the three challenged settlements—are alleged facts that show *any payment at all*, much less one that "exceeds $300 million." *Id.* at 11. Conclusory assertions that the Amended Complaint "contains detailed facts" get them no further. *Id.* at 38; *see Actos*, 2015 WL 5610752, at *19; *In re Loestrin*, 814 F.3d at 552. Plaintiffs have copies of the settlements, and have no license to speculate about payments nowhere to be found in those documents.

III. CELGENE'S PATENT PROSECUTIONS ARE IMMUNE FROM ANTITRUST LIABILITY, AND PLAINTIFFS DO NOT PLAUSIBLY PLEAD OTHERWISE.

By declining to address *almost any* of the grounds for dismissing their *Walker Process* claims, Plaintiffs suggest their Amended Complaint is so self-evidently plausible that defending it is unnecessary. By failing to front even a nominal defense to these deficiencies, Plaintiffs have conceded them. Rather than engage with any of the legal deficiencies, Plaintiffs insist that there must be "disputes of fact." Opp. at 19.

Plaintiffs lack standing to bring a *Walker Process* challenge, fail to plausibly plead one in any event, and fail to plausibly plead that every single litigation asserting those patents was a sham.

A. Plaintiffs Lack Antitrust Standing to Challenge Patents Issued Years Later.

Plaintiffs are unable to identify *even a single* case holding that indirect purchasers have antitrust standing to bring *Walker Process* claims.

Rather than reckon with the only Second Circuit authority on point—*In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009)—Plaintiffs observe (Opp. at 20) only that *DDAVP* "outline[d] a set of factors that courts can consider when determining a party's [antitrust] standing." Celgene addressed those factors head on—they confirm no standing. MTD at 22-23. But Plaintiffs address none of them, suggesting instead that this Court "need not decide" antitrust standing until class certification. Opp. at 20 & n.93. This is wrong. Antitrust standing is a "threshold, pleading-stage" matter, *In re Am. Express Anti-Steering Rules Antitrust Litig.*, 19 F.4th 127, 138 (2d Cir. 2021) (cleaned up); *see Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 770 (2d Cir. 2016), and the Court should not indulge Plaintiffs' effort to delay resolution of their antitrust standing. Plaintiffs have failed to make the required threshold showing, putting forth a complaint that reveals them to be improper antitrust plaintiffs under the efficient-enforcer factors. *See, e.g.*, *In re Am. Express*, 19 F.4th at 139-41 (explaining that derivative injuries like those Plaintiffs allege

here are too remote to satisfy the Second Circuit's "first-step rule," which is grounded in principles of proximate cause and applies in the antitrust context); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 542 (E.D.N.Y. 2005). Again, Plaintiffs address none of these factors, much less explain what would be different at class certification; to state the obvious, Plaintiffs would still be indirect purchasers—several steps removed from the grant of patents to Celgene—were this case to reach that stage. MTD at 22-23.

Plaintiffs also obfuscate by citing four cases that discussed *preemption*—an issue Celgene never raised. Opp. at 20 & n.89 (collecting cases). Plaintiffs also cite an opinion on remand in *DDAVP*, but ignore that it was not about antitrust standing—it was about *Article III* standing. *Id.* at 20 & n.93 (citing 903 F. Supp. 2d 198, 213 (S.D.N.Y. 2012) (discussing "Article III standing determination[s]")). Celgene's (unrebutted) position here is that Plaintiffs, as indirect purchasers, lack antitrust standing. *See, e.g.*, *In re Digit. Music Antitrust Litig.*, 812 F. Supp. 2d 390, 400-01, 404 (S.D.N.Y. 2011) (observing that, "[i]n addition to Article III standing, an antitrust plaintiff must also establish antitrust standing," and applying factors from Second Circuit's *In re DDAVP* decision to conclude that plaintiffs failed to establish the latter); *id.* at 416 (finding—separately from the standing inquiry—no preemption).[3]

Plaintiffs rely on the lack of a "Second Circuit decision holding that end payors lack standing." Opp. at 21. But courts that *have* addressed *Walker Process* standing conclude that it "does not confer standing on a party whose only connection to the patentee is as an indirect purchaser of products covered by the patent," *Farag v. Health Care Serv. Corp.*, 2017 WL 2868999, at *4-6 (N.D. Ill. July 5, 2017), and the most relevant Second Circuit decision supports

[3] Plaintiffs also mischaracterize (Opp. at 20) *Walker Process* itself, which never even spoke of or addressed standing. As Plaintiffs concede, the plaintiff in *Walker Process* was a competitor, *not* an indirect purchaser. *Id.*

the same conclusion. *See In re DDAVP*, 585 F.3d at 691 (expressing reservations about "disturbing the incentives for innovation" by unduly "expanding the universe of patent challengers").

Finally, it is of no moment that Plaintiffs are able to make a list of cases that happen to have involved indirect purchaser *Walker Process* claims, Opp. at 21 n.96, for as Plaintiffs explicitly concede, none of those cases "even addressed the issue" of standing at all, *id.* at 21. *See, e.g.*, *Ontario Pub. Serv. Emps. Union Pension Tr. Fund v. Nortel Networks Corp.*, 369 F.3d 27, 33 (2d Cir. 2004) (rejecting as "unreasonable" plaintiffs' argument that court "implicitly" found standing where opinion never "explicitly addressed the standing requirement").

B. Plaintiffs Fail to Adequately Plead *Walker Process* Fraud.

Even if Plaintiffs had standing, they fail to adequately plead—under the demanding standards of Rule 9(b) and *Exergen*—that Celgene acquired its patents by fraud. Celgene's Motion identified the facially obvious legal flaws in Plaintiffs' *Walker Process* claims. Plaintiffs offer *almost no arguments* in response. Instead, Plaintiffs' rebuttal distills, in large part, to only a single point: that there are purportedly "disputes of fact." Opp. at 19. This is not a substantive response.

First, each of the legal deficiencies pointed out in Celgene's Motion is based on citation to specific pages of the administrative record, *i.e.*, the very record Plaintiffs relied on in bringing their claims.[4] Plaintiffs cannot avoid Celgene's Motion by simply relying on factual allegations that are contradicted by those incorporated documents. *Bogie v. Rosenberg*, 705 F.3d 603, 609 (7th Cir. 2013) (affirming dismissal when pleaded facts were contradicted by attached exhibits). Certainly, Plaintiffs cannot wave issues away as "disputes of fact" without even specifying what that factual dispute is. In several instances, the record reflects that Celgene disclosed the very

[4] Plaintiffs do not dispute that this administrative record is both judicially noticeable and incorporated into the Amended Complaint and therefore is of record here. MTD at 26 n.12.

information that Plaintiffs claim it "hid" and so "lied" about[5]; if Plaintiffs are unwilling to concede error in their review of the record, so be it, but they cannot simply declare "fact disputes."

Second, as to each patent, there are legal deficiencies, unrebutted by Plaintiffs, that in and of themselves compel dismissal even without resort to the incorporated record. *See* Appendix 2 (listing the legal grounds for dismissal, and Plaintiffs' omission of responses thereto). Plaintiffs do not address that (i) Celgene had no legal duty to explain sources it disclosed (MTD at 35-36); (ii) Celgene offered only legal argument to try to distinguish the '517 patent and Davies (2001) reference (*id.* at 31, 34-35); (iii) Thakurta submitted *unactionable opinions* to the PTO which are not representations of fact (*id.* at 39); (iv) the examiner *expressly did not rely* on Celgene's statements with regard to the '517 patent (by withdrawing his rejection for other reasons)[6] or the '467/'5939 patents (by declining to find unexpected results) (*id.* at 32-33, 42); and (v) repeatedly, Plaintiffs speak of a "misstatement," "omission," or "false" data, without identifying *what the misstatement, omission or false data was*, despite the Rule 9(b) standard for *Walker Process* claims (*id.* at 37-38, 42). Plaintiffs cannot avoid dismissal simply by ignoring the materiality, non-cumulativeness, knowledge, and reliance elements of their fraud claims.

Third, Plaintiffs attempt to rewrite their allegations in the Opposition. Plaintiffs initially made a big splash of accusing Celgene of "bury[ing]" patents and patent applications issued to D'Amato, insisting that Celgene "conceal[ed] that D'Amato . . . taught" the Pomalyst inventions. ECF 98 at 2. But now, after Celgene moved to dismiss on the ground that *every single D'Amato*

[5] *E.g.*, MTD at 34 (noting Plaintiffs admit that the information Celgene allegedly hid about the '517 was disclosed in the '230 and '554); *id.* at 37 (noting Plaintiffs admit that a teaching they claim Celgene misrepresented was "fully encompassed" in a source Celgene indisputably disclosed).

[6] Emblematic of Plaintiffs' distract-rather-than-engage approach is how they address the undisputed fact that the examiner did not rely on Celgene's representations regarding the '517 because he *expressly* withdrew his rejection for different reasons. *See* MTD at 32-33; MTD Ex. D at 79, 90. Plaintiffs now claim instead that Celgene "trick[ed] the examiner into withdrawing" the rejection. Opp. at 19-20. This is nowhere pleaded—it is totally made up.

patent or application Plaintiffs raised was in fact disclosed to the PTO, Plaintiffs try to reframe their fraud claims as having nothing to do with those (apparently not "buried") patents. *See* Opp. at 17 n.79 ("The *Walker Process* fraud allegations do not rest on those allegations[.]"). This is only one example of Celgene pointing to record confirmation that it disclosed the very same information that Plaintiffs claimed Celgene "hid," and Plaintiffs effectively conceding that their allegations of misrepresentation or omission are entirely false. This opportunistic approach—lobbing, but then walking away from, baseless allegations—does not suffice to state a claim.

This leaves Plaintiffs with a handful of flawed arguments. They say they need only show the examiner would have found the allegedly withheld information "important." Opp. at 18 (citing *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 2007 WL 1437834, at *20 (S.D.N.Y. May 14, 2007)). While the information was never withheld anyway, "important" is not the standard. Plaintiffs need "particularized allegations that *'but for' the omissions,* the PTO would not have granted" a specific claim of the patent. *Radiancy, Inc. v. Viatek Consumer Prods. Grp., Inc.*, 138 F. Supp. 3d 303, 324 (S.D.N.Y. 2014) (emphasis added) (cleaned up); *see also* Opp. at 16 (citing *In re DDAVP*, 585 F.3d at 685). Plaintiffs must also identify "the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009). In other words, they must plead "both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing [] patentability[.]" *Id.* at 1329-30; *see also Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (materiality requires that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art").[7]

[7] Plaintiffs' only citation for their "important" standard (*Eisai*) was abrogated by *Therasense* (and *Exergen*), wherein the Federal Circuit raised the already-demanding standard for moving forward with such claims in order to "redirect a doctrine that" "has plagued not only the courts but also the entire patent system." *Therasense*, 649 F.3d at 1289-90. That is why, since *Therasense*, *Eisai* has never once been cited for the proposition for which Plaintiffs wield it now.

The Amended Complaint does not clear these hurdles for *any* misrepresentation Plaintiffs allege. Never once do Plaintiffs allege with specificity a missing claim limitation in the record, nor do they ever identify how any source they claim is missing or misrepresentation they claim Celgene made would have resulted in denial of a specific claim. Plaintiffs try to shift the burden to Celgene (Opp. at 19), but it is *Plaintiffs'* burden to plead "'why' the withheld information is material and not cumulative." *Exergen*, 575 F.3d at 1329-30.

Finally, Plaintiffs argue that the Court "must look at the fraud collectively." Opp. at 19 (citing *Luv n' Care, Ltd. v. Laurain*, 2024 WL 1590593, at *8 (Fed. Cir. Apr. 12, 2024)). How that would help Plaintiffs here, they do not say. *Luv n' Care* spoke of reviewing a pattern of conduct in order to circumstantially "support a finding *of deceptive intent*." 2024 WL 1590593, at *8 (emphasis added); *see also* Opp. at 19 n.87 (citing three other cases for the same proposition related to intent). It is of no moment that *intent* can be inferred from other facts under Rule 9(b)—Plaintiffs offer zero such facts here, and this is just another strawman that has nothing to do with the legal deficiencies in Plaintiffs' pleading a supposed *Walker Process* fraud.

C. Plaintiffs Apply the Incorrect Standard for Sham Litigation, and Do Not Plausibly Plead That Celgene's Suits Were Shams.

Plaintiffs insist that this Court must put to a jury whether Celgene's suits were sham. They are again wrong: courts in this Circuit and elsewhere dismiss just these sorts of claims on Rule 12(b)(6) motions all the time.[8] That is because the Court can decide the issue as a matter of law where "there is no dispute over the predicate facts underlying the legal proceeding." *In re Elysium*

[8] *See, e.g.*, *Radiancy*, 138 F. Supp. 3d at 324 (dismissing *Walker Process* and sham litigation claims); *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 58-62 (2d Cir. 2016); *AstraZeneca AB v. Mylan Labs., Inc.*, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010), *aff'd*, 412 F. App'x 297 (Fed. Cir. 2011); *Bath Petroleum Storage, Inc. v. Mkt. Hub Partners, LP*, 229 F.3d 1135 (2d Cir. 2000) (unpublished); *Marchon Eyewear, Inc. v. Tura, LP*, 2002 WL 31253199, at *7-9 (E.D.N.Y. Sept. 30, 2002); *La. Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, 2021 WL 4988523, at *10 (D.N.J. Oct. 27, 2021); *UFCW v. Novartis Pharms. Corp.*, 2017 WL 2837002, at *15-16 (D. Mass. June 30, 2017); *Avery Dennison Corp. v. Cont'l Datalabel, Inc.*, 2010 WL 4932666, at *5-6 (N.D. Ill. Nov. 30, 2010).

Health-Chromadex Litig., 354 F. Supp. 3d 330, 336 (S.D.N.Y. 2019) (quoting *Prof'l Real Est. Invs., Inc. v. Columbia Pictures Indus.* ("*PRE*"), 508 U.S. 49, 62 (1993)). Plaintiffs' sham litigation claims here flow entirely from their allegations of Celgene's "fraud" on the PTO, and courts routinely dismiss fraud claims where, as here, the incorporated record belies the fraud allegations. Claims of fraud on the PTO are routinely dismissed at the 12(b)(6) stage through reliance on public documents,[9] as are claims of fraud of other varieties.[10]

There are several additional, independent bases for dismissal of Plaintiffs' sham litigation claims. *First*, the patent suits here settled so as to respect several years of the remaining patent life. Absent unlawful provisions in the settlements (of which there are none here, *see supra*), the settlements were successful outcomes to the litigation that preclude any sham litigation claim. *See* MTD at 44-45 (collecting cases holding favorable settlements inconsistent with claims of sham litigation). *Second*, Plaintiffs do not respond to the legal reality that the generics' Paragraph IV dispute letters *themselves* provided a statutorily *invited* basis to sue. *See AstraZeneca AB*, 2010 WL 2079722, at *4; MTD at 44. *Third*, though they spend four pages rehashing their Amended Complaint (*see* Opp. at 24-27), Plaintiffs cannot muster any non-conclusory allegation plausibly demonstrating how a reasonable litigant would have known at the time lawsuits were filed that Celgene's patents were "obviously invalid" and that the generics "plainly [did] not infringe[]." *Globetrotter Software, Inc. v. Elan Comput. Grp.*, 362 F.3d 1367, 1375 (Fed. Cir. 2004). *Fourth*,

[9] *See, e.g.*, *Viva Optique, Inc. v. Contour Optik, Inc.*, 2007 WL 4302729, at *2 (S.D.N.Y. Dec. 7, 2007); *Jersey Asparagus Farms, Inc. v. Rutgers Univ.*, 803 F. Supp. 2d 295, 306-12 (D.N.J. 2011); *Certainteed Gypsum, Inc. v. Pac. Coast Bldg. Prods., Inc.*, 2021 WL 5449073, at *10-12 (N.D. Cal. Nov. 22, 2021); *Ill. Tool Works Inc. v. Termax LLC*, 2023 WL 4707263, at *8-10 (N.D. Ill. July 24, 2023); *Power Integrations, Inc. v. ON Semiconductor Corp.*, 2018 WL 1438767, at *3-4 (N.D. Cal. Jan. 17, 2018).

[10] *See, e.g.*, *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773-74 (2d Cir. 1991) (affirming dismissal in securities fraud case considering public disclosure documents filed with the SEC); *DarkPulse, Inc. v. FirstFire Glob. Opportunities Fund, LLC*, 2023 WL 199196, at *3 n.7, *6 (S.D.N.Y. Jan. 17, 2023) (dismissing after judicial notice of prospectus and other public filings), *aff'd in part, vacated in part on other grounds*, 2024 WL 1326964 (2d Cir. Mar. 28, 2024); *In re UBS Auction Rate Secs. Litig.*, 2010 WL 2541166, at *7, *17 (S.D.N.Y. June 10, 2010) (same).

while Plaintiffs argue that Celgene's "attacks on the sham allegations are factual disputes," they again do not identify what those factual disputes are.

The only arguments Plaintiffs offer specifically pertaining to the assertion of the patents against the generics are makeweight. With regard to the method-of-treatment patents, Plaintiffs make the bewildering claim that the patent court's "June 2020 *Markman* decision"—in which it ruled *for* Celgene on several terms and against Celgene on only one—"eliminated any continued pretense that the patents were valid." Opp. at 25. It is impossible to fathom how an intermediate ruling largely in favor of Celgene, and against the generics, could plausibly suggest sham litigation. In any event, Celgene was not "require[d] . . . to divine the outcome of claim construction before filing," a point "especially true in the Hatch-Waxman context[.]" *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 151 n.22 (3d Cir. 2017); *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 223 (S.D.N.Y. 2002) (alleged sham suit evaluated by looking to the point in time it was filed).[11]

As to the polymorph patents, Plaintiffs argue that "even if" they were valid[12] Celgene could not "expect to prevail" on them, because to "infringe all three patents, an ANDA product would have to be comprised of three different hydrates." Opp. at 26. Asserting multiple polymorph patents is not unusual, *see, e.g.*, *Lundbeck v. Apotex Inc.*, 2020 WL 3507795, at *1 (D. Del. June 26, 2020) (four polymorph patents), and Plaintiffs plead no facts as to how that was somehow

[11] And even as regards the single term for which the court ruled against Celgene, the court repeatedly expressed just how difficult a question it was. *Celgene Corp. v. Hetero Labs Ltd.*, 2:17-cv-03387 (D.N.J. Feb. 26, 2020), ECF 650, at 87:25 ("[Q]uite frankly, this [term] is the closest call for me."), 95:13-14 ("I, quite frankly, have a lot to think about."), 96:15 ("[I]'ve changed [my] mind five times inside."), 97:15-16 ("I am struggling . . . with, obviously, the preamble issue and the lubricant terms."). No one, least of all the court, suggested that Celgene's position on that one term was frivolous so as to demonstrate the entire case was a sham.

[12] Plaintiffs do not address that nothing in their allegations "plead[s] [that] any particular disclosure in the Paragraph IV letters [] rendered Celgene's polymorph patents invalid." MTD at 48. Plaintiffs thus concede these patents are not invalid.

inappropriate in the case of Pomalyst.[13] Certainly, Plaintiffs have not pleaded that Celgene had exhaustive information from each generic as of the time it filed its suits as to the polymorphs present in their products. This was all set forth in Celgene's Motion (at 48-49), and Plaintiffs waived any response.

Plaintiffs are left to suggest that even if they are unable to plead that any particular one of the Pomalyst patent suits was so baseless that no reasonable person could expect success, *see PRE*, 508 U.S. at 60, they could nevertheless prevail on a claim for "serial petitioning" simply on the basis that Celgene sued not one but nine generics. Opp. at 22-23. That is ridiculous on its face: Celgene sued the nine generics that served the Paragraph IV certifications constituting statutory acts of infringement. 35 U.S.C. § 271(e)(2). A serial petitioning claim "is particularly inapt" in that context, courts have explained, because suing every generic on every patent a pharmaceutical manufacturer obtains is "consistent with the design and intent of Hatch-Waxman." *Wellbutrin*, 868 F.3d at 157-58. The *number* of suits a patentee files—what Plaintiffs call "waves" of suits here—is "dependent on the number of generic companies attempting to enter the . . . marketplace, a matter over which [the patentee] had no control." *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009); *see also Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 2009 WL 8727693, at *10 (C.D. Cal. Feb. 17, 2009) ("The volume of [the patentee's] suits in the Hatch-Waxman context matters little, if at all.").[14] This Court should follow

[13] The counterfactual world Plaintiffs argue in their Opposition—that Celgene would have to show the generics infringed *all three patents*—is inconsistent with their Amended Complaint, which alleged only that Celgene "would be required to establish that all nine ANDA products were a dihydrate, hemihydrate, *or* monohydrate," Am. Compl. ¶ 284 (emphasis added), and then asserted, without reasoning, that this was "impossible," *id.*

[14] Plaintiffs identify only a single, outlier district court case, *Blue Cross & Blue Shield of Vt. v. Teva Pharmaceutical Industries, Ltd.*, 2024 WL 323775 (D. Vt. Jan. 22, 2024), and its reasoning does not stand. It misreads *AbbVie*, 976 F.3d 327, to conclude the Third Circuit determines whether to apply a serial petitioning standard on a case-by-case basis. But that is wrong. The *AbbVie* court *reaffirmed Wellbutrin* that to apply a serial petitioning standard to Hatch-Waxman litigants would "penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.'" *Id.* at 361 (cleaned up). Indeed, the court did not apply the serial petitioning standard there, and courts

this overwhelming weight of authority, along with the *AstraZeneca*, *Radiancy*, and *Apotex* courts, and dismiss Plaintiffs' sham litigation claims for failure to plausibly plead that Celgene's suits were objectively baseless.

CONCLUSION

The Court should dismiss with prejudice.

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within the Third Circuit read *AbbVie* and *Wellbutrin* to foreclose the serial petitioning standard in the Hatch-Waxman context. *Janssen Biotech*, 2021 WL 4988523, at *8 n.20.

APPENDIX 2

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Allegation	Defendants' MTD (ECF 109)	Plaintiffs' Opp. (ECF 127)
'262 Patent: Alleged misrepresentation that '517 patent did not teach pomalidomide ("pom") (Am. Compl. ¶¶ 168-74) *All citations to paragraphs are to the Amended Complaint (ECF 69).*	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead how the alleged misrepresentation was but-for material to the amended claims that ultimately issued (MTD at 29) 2. **No actionable representation**: Statements were argument to *distinguish* the '517 from the claims (MTD at 30-31) 3. **Disclosed**: Celgene disclosed that the '517 patent taught pom in its 2008 application (MTD at 31-32) 4. **No reliance**: Examiner admitted he mis-cited the reference, he withdrew the rejection, and he did not rely on the challenged statement (MTD at 32-34) 5. **Cumulative**: Examiner concluded that the disclosed '230/'554 patents made the same disclosure as the alleged '517 disclosure (MTD at 34)	1. No response; admitted at ¶ 193 2. Unidentified "dispute of fact" (Opp. at 19) 3. No response 4. Celgene supposedly "tricked" examiner into withdrawing previous rejection. Opp. at 19-20 (wrong source admitted at ¶¶ 168, 185) 5. No response; admitted at ¶ 123
'262 Patent: Alleged misrepresentation that Davies 2001 did not teach using pom to treat multiple myeloma ("MM") (¶ 175)	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead how the alleged misrepresentation was but-for material to the amended claims that ultimately issued (MTD at 29) 2. **No actionable representation**: Statements were *argument* that Davies 2001 did not identify it by chemical name or structure (MTD at 35) 3. **Immaterial**: Plaintiffs do not plead how anything said with respect to Davies 2001 was material to an issued claim (MTD at 35)	1. No response 2. No response 3. No response
'262 Patent: Alleged omission that D'Amato 2001 taught using pom to treat MM (¶¶ 176-82)	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead how the alleged misrepresentation was but-for material to the amended claims that ultimately issued (MTD at 29) 2. **Disclosed and no legal duty to explain a source**: Celgene in fact *disclosed* D'Amato 2001, and had no legal obligation to explain it (MTD at 35-36)	1. No response 2. No response
'262 Patent: Alleged misrepresentation that use of pom to treat MM had not been disclosed publicly (¶ 187 & n.72)	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead how the alleged misrepresentation was but-for material to the amended claims that ultimately issued (MTD at 29) 2. **No representation**: Statement was directed to *examiner's* cited sources, not to Plaintiffs' five sources (MTD at 36-37) 3. **Disclosed/Cumulative**: Celgene *disclosed* 4 of 5 sources Plaintiffs claim had this teaching, including one that "fully encompassed" the teaching (MTD at 37)	1. No response 2. No response; admitted at ¶ 187 n.72 3. No response; admitted at ¶ 187
'262 Patent: Alleged misrepresentation that "use of one thalidomide	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead materiality for claims that differed from those issued (MTD at 29)	1. No response

compound over another had not been" publicly disclosed (¶ 188)	2. **No 9(b) specificity**: Plaintiffs allege "misleading statements and material omissions," but *do not identify any specific statement/omission* (MTD at 37) 3. **Immaterial**: Plaintiffs do not allege how specific claims in the '262 patent would not have issued but for the misstatement or omission (MTD at 37)	2. No response 3. No response
'262 Patent: Alleged misrepresentation that pom produced unexpected results for treating relapsed or refractory MM (¶ 189)	1. **Immaterial**: Celgene subsequently amended claims, and Plaintiffs do not plead how the alleged misrepresentation was but-for material to the amended claims that ultimately issued (MTD at 29) 2. **No 9(b) specificity**: Plaintiffs allege misrepresentation of "unexpected results," but *do not identify where Celgene said it or what the results were* (MTD at 37) 3. **Immaterial**: Plaintiffs do not allege how specific claims in the '262 patent would not have issued but for the misstatements or omissions (MTD at 37)	1. No response 2. No response 3. No response
'262 Patent: Alleged misrepresentation that the prior art did not teach cyclical dosing (¶¶ 191-92)	1. **No 9(b) specificity**: Plaintiffs do not identify an actual statement or omission Celgene made to the examiner (MTD at 38) 2. **Immaterial**: Plaintiffs do not allege how the specific claims in the '262 patent would not have issued but for the misstatements or omissions (MTD at 38)	1. No response 2. No response
'428/'3939 Patents Alleged misrepresentation in Thakurta declaration of "surprising" results that pom was effective in treating relapsed or refractory MM (¶¶ 225-28)	1. **No 9(b) specificity**: Plaintiffs do not allege any fraudulent misrepresentation in Thakurta's CV (MTD at 38-39) 2. **No actionable statement**: Declarant's opinion is not a factual representation (MTD at 39) 3. **Immaterial**: Plaintiffs do not allege how the examiner would have rejected specific issued claims had the declaration not been submitted (MTD at 39) 4. **Disclosed and no pled knowledge**: Plaintiffs do not allege Thakurta knew about sources they identify such that he could knowingly misrepresent them, and ignore that Celgene cited four of them (MTD at 40)	1. No response 2. No response 3. No response 4. No response
'427 Patent: Alleged omission of Schey (April 2002), which taught a 5 mg/day dosage for pom (¶ 201)	1. **Immaterial**: Plaintiffs do not allege how the examiner would have rejected specific issued claims had the source been submitted (MTD at 41) 2. **No pled knowledge**: Plaintiffs do not allege that Celgene *knew* that the source was material and then chose to omit it (MTD at 41) 3. **Cumulative**: Plaintiffs do not allege how the source was noncumulative since the examiner interpreted different art to teach the same (MTD at 41)	1. No response 2. No response 3. No response
'428/'3939/'427 Patents: "False" declaration claiming unexpected results, relying on "false," "undated" data (¶¶ 212-14)	1. **No actionable statement**: "Undated" data is not actionable (MTD at 41-42) 2. **No 9(b) specificity**: Plaintiffs do not identify *what* allegedly "false" data Tutino purportedly relied on (MTD at 42) 3. **No reliance**: Examiner *expressly declined to rely on* the challenged argument (MTD at 42)	1. No response 2. No response 3. No response